Exhibit 3

Gynecare

PROLIFT™

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Totalt reparationssystem til bækkenbunden
Reparationssystem til anteriore bækkenbund
Reparationssystem til posteriore bækkenbund

Bekkenbodemreparatiesysteem totaal
Bekkenbodemreparatiesysteem anterieur
Bekkenbodemreparatiesysteem posterieur

Totaalinen lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système de reconstruction totale du plancher pelvien
Système de reconstruction antérieure du plancher pelvien
Système de reconstruction postérieure du plancher pelvien

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

CE 0086
Manufactured for:
ETHICON Women's Health & Urology
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

EC
Legal Manufacturer
ETHICON, Sàrl
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CH-2000 Neuchâtel
Switzerland

P19070/H
STATUS: 02/2010
LAB0011099.2

Gynecare PROLIFT™

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: **Federal (USA) law restricts this device to sale by or on the order of a physician.**

Training on the use of the GYNECARE PROLIFT™ Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training. Physicians should have experience in management of complications resulting from procedures using surgical mesh.

Refer to the recommended surgical technique guide for the GYNECARE PROLIFT™ Systems for further information on the pelvic floor repair procedure. Contact your company sales representative to obtain this surgical technique guide.

The safety and effectiveness of the GYNECARE PROLIFT™ Systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the GYNECARE PROLIFT™ Systems to synthetic mesh with the same indication has been demonstrated through benchtop and cadaveric testing. Information on the clinical performance of mesh for pelvic floor repair is available in published literature. Contact your company sales representative for assistance.

INDICATIONS

The GYNECARE PROLIFT™ Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

- **GYNECARE GYNEMESH™ PS Mesh should not be used in infants, children, pregnant women, or women planning future pregnancies, as the mesh will not stretch significantly as the patient grows.**
- **GYNECARE GYNEMESH™ PS Mesh must always be separated from the abdominal cavity by peritoneum.**
- **GYNECARE GYNEMESH™ PS Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.**
- **The GYNECARE PROLIFT™ Systems should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.**

WARNINGS

- **Patients on anticoagulation agents undergoing surgery using the GYNECARE PROLIFT™ System must have their anticoagulation therapy carefully managed.**
- **Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.**
- **A digital rectal exam should be performed to detect possible rectal perforation.**
- **Cystoscopy may be performed to confirm bladder and ureteral integrity.**
- **Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.**
- **Use the GYNECARE PROLIFT™ Systems with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and to avoid vaginal wall perforation. Correct use of the GYNECARE PROLIFT™ Systems components will minimize risks.**
- **Transient leg pain may occur and can usually be managed with mild analgesics.**

PRECAUTIONS

- **Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT™ Systems.**
- **Avoid placing excessive tension on the mesh implant during placement.**
- **Do not manipulate the GYNECARE PROLIFT™ Retrieval Device with sharp instruments or cut it to alter its length.**
- **Do not affix the GYNECARE GYNEMESH™ PS Mesh Implant with any staples, clips, or clamps as mechanical damage to the mesh may occur.**
- **This product should only be used under the prescription of a physician.**

- **In patients with compromised immune systems or other conditions that would compromise healing the risks and benefits should be carefully weighed.**
- **Vaginal or urinary tract infection should be treated and alleviated prior to implantation.**
- **Acceptable surgical practice should be followed for the GYNECARE PROLIFT™ Systems as well as for the management of infected or contaminated wounds. If the Mesh Implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.**
- **Prolapse repair may unmask pre-existing incontinence conditions.**
- **Prophylactic antibiotics can be administered according to the surgeon's usual practice.**
- **The use of this product with tissue adhesives is not recommended, as data are not currently available.**

ADVERSE REACTIONS

- **Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureteral obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.**
- **Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.**
- **Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.**
- **Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.**

CLINICAL PERFORMANCE

Randomized, controlled clinical evaluations of the GYNECARE PROLIFT™ System are underway, but at this time preliminary data are available from two early observational studies of transvaginal mesh that were initiated in 2004. These observational studies evaluated a pre-cut surgical mesh made of the same non-absorbable polypropylene as the mesh used in the GYNECARE PROLIFT™ System. For these studies, the mesh was provided in shape similar to that of the GYNECARE PROLIFT™ System, though implantation instruments were not provided in these studies. One of the two studies involved eight investigational centers in France; the second included three investigational centers in the US. The protocols were similar, where both studies were conducted to evaluate the usability of a pre-cut mesh for anterior, posterior, and vault prolapse in women with symptomatic prolapse of at least ICS Stage III using the precut mesh and a transvaginal surgical technique.

The inclusion criteria for both studies were as follows: symptomatic prolapse of at least ICS Stage III, subjects at least 21 years of age, subjects do not wish to become pregnant in the future, no uncontrolled diabetes, and no coagulation disorder. In the French study, an additional inclusion criterion was a prior or concurrent hysterectomy. The primary effectiveness endpoint for both studies was the proportion of subjects for whom correction of prolapse was achieved (ICS Stage 0 or I) evaluated at 12 months post-operatively. Secondary endpoints for both studies included: vaginal prolapse occurring in the area not treated with mesh, peri-operative complications, patient tolerance of synthetic mesh, post-operative complications, and quality of life (QOL). An additional secondary endpoint for the US study was the recurrence rate of vaginal prolapse in the area treated with mesh. Study populations available for follow-up at 12 months were 83 patients in the US and 87 patients in France with a median patient age of 62 and 66.5, respectively.

The 12-month postoperative study results were as follows (US, France): proportion of subjects with ICS Stage II or greater (12.0%, 18.4%), met pre-defined criteria of upper limit of 90% CI less than 20% (yes, no), Prolapse Symptom Index (PSI) mean (6.6, 3.1), Mean QOL score (0.7, 0.4).

Adverse events, expressed as percentages, were as follows (US, France): hematoma (3.5, 4.5), abscess (0, 1.1), urinary tract infection within 6 weeks post-procedure (8.2, 16.9), mesh exposure (14.1, 10.0), surgical intervention for mesh exposure (7.1, 5.6), vesico-vaginal fistula (1.2, 1.1), recto vaginal fistula (1.0, 0), moderate/severe vaginal retraction (3.6, 12.6).

More recent data specific to the GYNECARE PROLIFT™ System may be available in the published literature. Please contact your sales representative for more information.

DESCRIPTION

The GYNECARE PROLIFT™ Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH™ PS Nonabsorbable PROLENE® Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT™ Pelvic Floor Repair System Components

GYNECARE GYNEMESH™ PS

GYNECARE GYNEMESH™ PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE® Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE® monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE® mesh. The mesh is knitted by a process which interlinks each fiber junction. This construction permits the mesh to be cut into any desired shape or size without unraveling.

Total Mesh Implant

The Total mesh implant is constructed from GYNECARE GYNEMESH™ PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1)*.

Anterior Mesh Implant

The Anterior mesh implant is constructed from GYNECARE GYNEMESH™ PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1)*.

Posterior Mesh Implant

The Posterior mesh implant is constructed from GYNECARE GYNEMESH™ PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1)*.

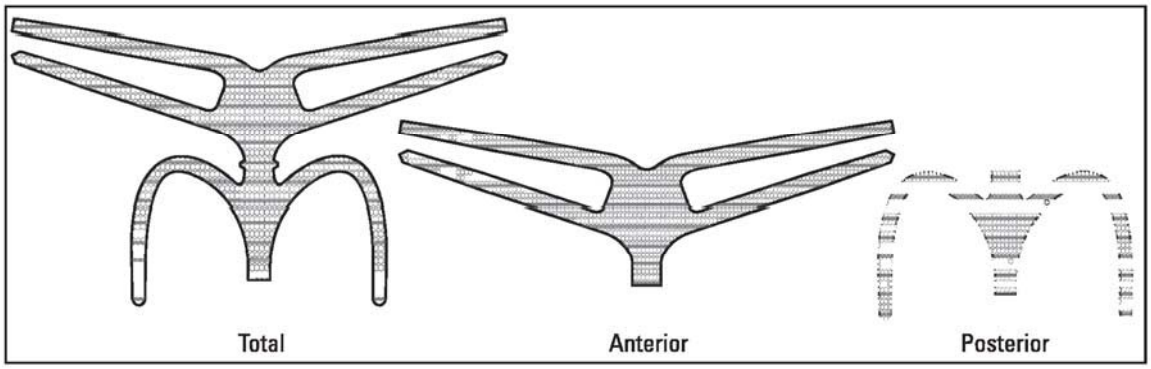

Figure 1 – Mesh Implants (Total, Anterior, and Posterior)

GYNECARE PROLIFT™ Guide

The GYNECARE PROLIFT™ Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT™ Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT™ Guide is suitable for use on both sides of the patient *(see Figure 2)*.

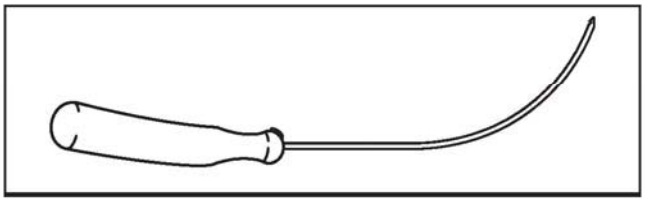

Figure 2 – GYNECARE PROLIFT™ Guide

GYNECARE PROLIFT™ Cannula

The GYNECARE PROLIFT™ Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT™ Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT™ Cannula is placed over the GYNECARE PROLIFT™ Guide prior to passage and remains in place after the GYNECARE PROLIFT™ Guide is withdrawn *(see Figure 3)*.

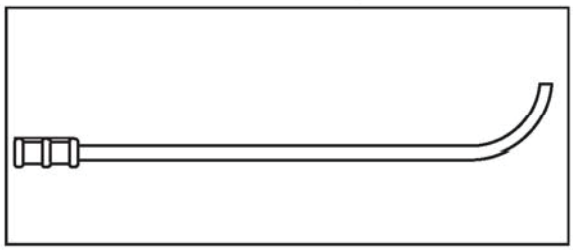

Figure 3 – GYNECARE PROLIFT™ Cannula

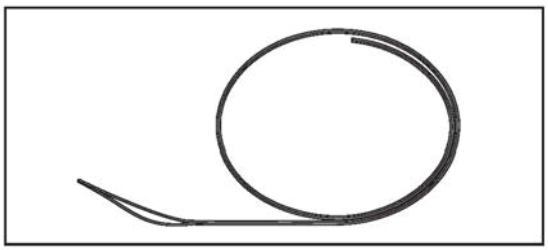

Figure 4 – GYNECARE PROLIFT™ Retrieval Device

GYNECARE PROLIFT™ Retrieval Device

The GYNECARE PROLIFT™ Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT™ Retrieval Device is passed through the previously positioned GYNECARE PROLIFT™ Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT™ Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT™ Cannula *(see Figure 4)*.

PERFORMANCE

Animal studies show that implantation of GYNECARE GYNEMESH™ PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

STERILITY

The GYNECARE PROLIFT™ Pelvic Floor Repair Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users. Do not use if package is opened or damaged. Discard all opened, unused devices.

DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

INSTRUCTIONS FOR USE

NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the GYNECARE PROLIFT™ Cannula onto the GYNECARE PROLIFT™ Guide *(See Figures 5A and 5B)*

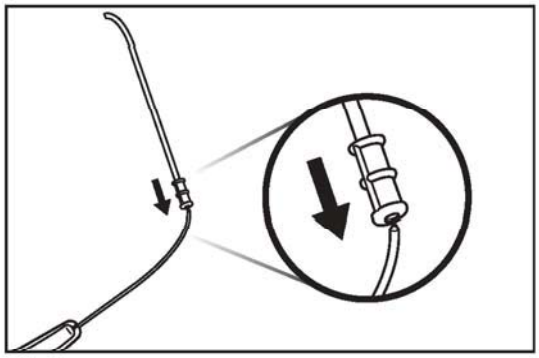

Figure 5A

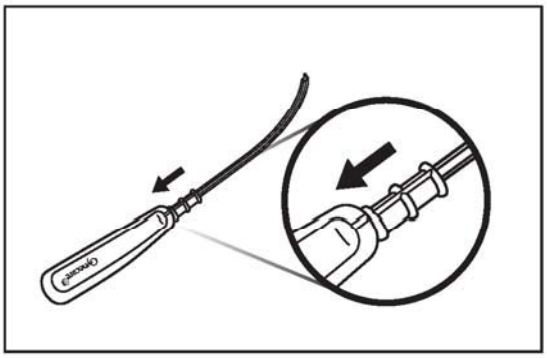

Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT™ Cannula and GYNECARE PROLIFT™ Guide upon assembly as demonstrated in Figure 5B.

Placement of the GYNECARE PROLIFT™ Cannula into the Patient ***(See Figures 6A, 6B and 6C)***

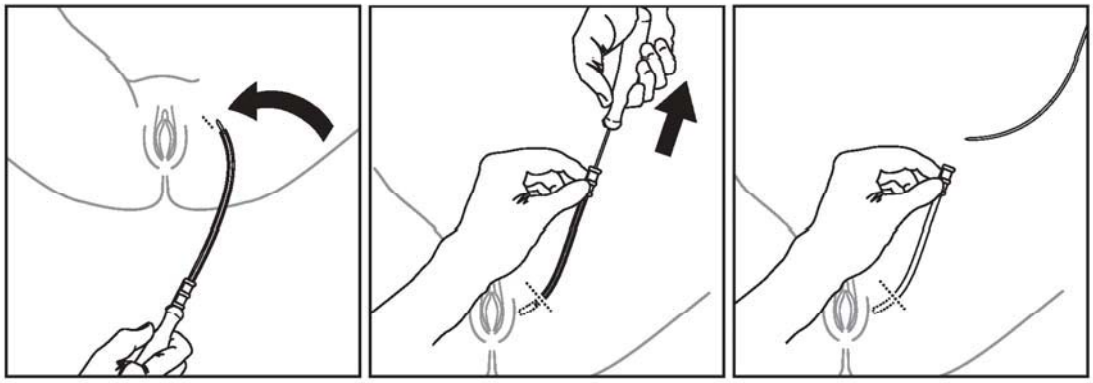

Figure 6A *Figure 6B* *Figure 6C*

Insertion and Passage of the GYNECARE PROLIFT™ Retrieval Device into the GYNECARE PROLIFT™ Cannula ***(See Figures 7A and 7B)***

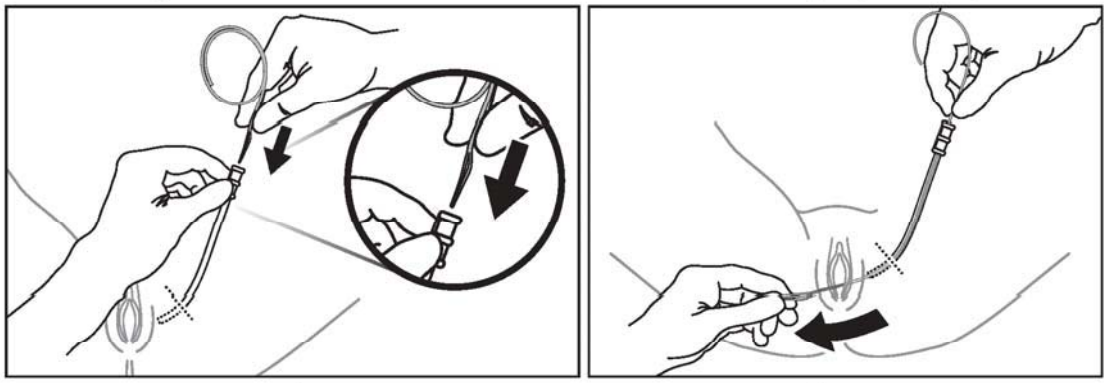

Figure 7A *Figure 7B*

IMPORTANT: All provided GYNECARE PROLIFT™ Cannulas and GYNECARE PROLIFT™ Retrieval Devices should be placed prior to mesh implant installation.

Capture of a Mesh Implant Strap with GYNECARE PROLIFT™ Retrieval Device ***(See Figures 8A, 8B and 8C)***

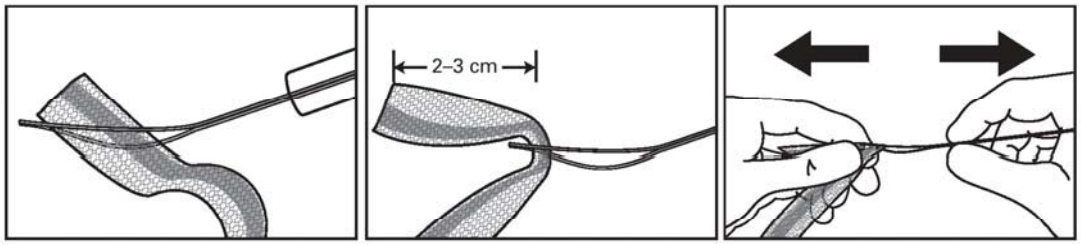

Figure 8A *Figure 8B* *Figure 8C*

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT™ Cannula ***(See Figures 9A, 9B and 9C)***

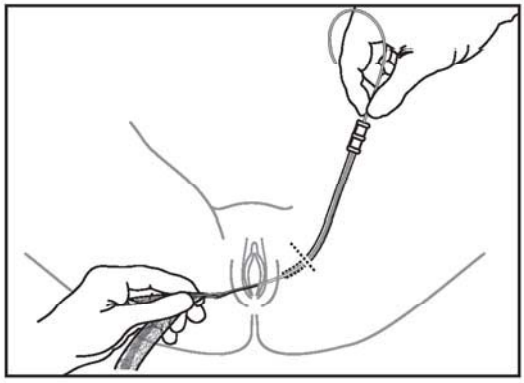

Figure 9A

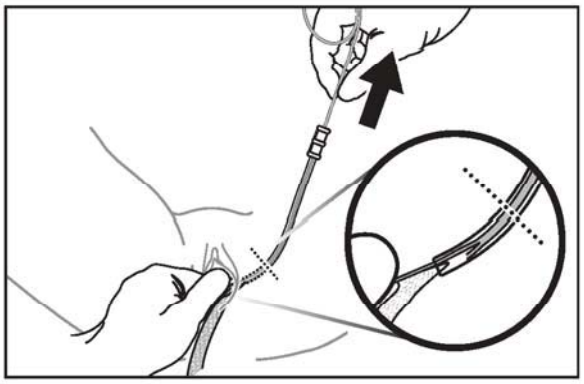

Figure 9B

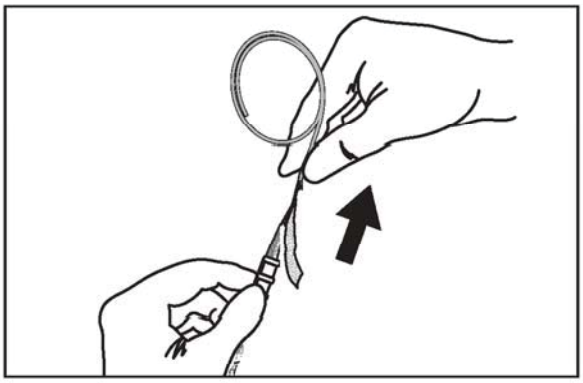

Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Symbols Used on Labeling

CE 0086 CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.	Manufacturer
	Do not reuse/resterilize
LOT Batch number	See instructions for use
Use by — year and month	STERILE EO Method of Sterilization — Ethylene Oxide